

WHAT IS CLAIMED IS:

- 1           1. A hand-held, portable, aerosol drug delivery system, comprising:  
2           a disposable container containing a drug formulation;  
3           an aerosol generator for aerosolizing the drug formulation;  
4           a prevention device which prevents access to the drug formulation when in  
5           an inactive state and which permits access to the drug formulation when in an activated  
6           state.
- 1           2. A system as in claim 1, wherein the prevention device comprises  
2           an electronic lockout device having a lockout element that is positioned in a dose  
3           preventing position when in the inactive state, and is movable to a dosing permitting  
4           position when electric current is supplied to place the lockout device in the activated  
5           state.
- 1           3. A system as in claim 2, wherein the lockout device further  
2           comprises circuitry for supplying electrical current to move the lockout element to the  
3           dose permitting position when the lockout device is in the activated state.
- 1           4. A system as in claim 2, wherein the lockout device further  
2           comprises a controller having an associated memory for storing a dosing condition, and  
3           wherein the controller is configured to send a signal to place the lockout device in the  
4           activated state only after the dosing condition has been satisfied.
- 1           5. A system as in claim 2, wherein the container comprises a canister,  
2           and wherein the aerosol generator comprises a metering valve and an actuator operably  
3           coupled to the canister.
- 1           6. A system as in claim 5, further comprising a housing, wherein the  
2           canister is reciprocally held within at least a portion of the housing between a home  
3           position and a dosing position where the actuator is engaged to open the metering valve  
4           and to permit the escape of a metered amount of the drug formulation from the canister.
- 1           7. A system as in claim 6, wherein the lockout element is positioned  
2           to prevent engagement of the actuator when in the dose preventing position to thereby  
3           prevent opening of the metering valve.

1                   8. A system as in claim 7, wherein the lockout element has a distal  
2 end that is engageable with the canister to prevent substantial displacement of the canister  
3 into the housing when the lockout element is in the dose preventing position.

1                   9. A system as in claim 8, wherein upon placement of the preventing  
2 device into the activated state, the distal end of the lockout element is retracted to permit  
3 displacement of the canister into the housing and to permit engagement of the actuator to  
4 open the metering valve.

1                   10. A system as in claim 7, wherein the canister is movable within the  
2 housing when the preventing device is in the inactive state, and further comprising a stop  
3 that is reciprocally disposed within the housing below the actuator, and wherein the  
4 lockout element has a distal end that is engageable with the stop when in the activated  
5 state to prevent movement of the stop within the housing such that displacement of the  
6 canister engages the actuator with the stop to permit dispensing of the metered drug  
7 formulation when the preventing device is in the activated state.

1                   11. A system as in claim 1, further comprising a high pressure gas  
2 source to assist in aerosolizing the drug formulation when the preventing device is in the  
3 activated state.

1                   12. A system as in claim 1, further comprising a dose counter disposed  
2 to count the number of doses of the drug formulation dispensed from the container.

1                   13. A system as in claim 12, wherein the container is reciprocatably  
2 disposed within a housing, and wherein the dose counter comprises a dose counting  
3 circuit positioned to sense when the container has been reciprocated within the housing.

1                   14. A system as in claim 13, wherein the dose counter further  
2 comprises a display for indicating if the container contains an amount of drug  
3 formulation.

1                   15. A system as in claim 5, further comprising a nozzle operable  
2 coupled to the canister, and wherein the housing further includes a mouthpiece disposed  
3 to receive the drug formulation from the nozzle.

1           16. A system as in claim 15, wherein the mouthpiece has a first end  
2 and a second end, and wherein the nozzle is positionable within an opening adjacent the  
3 first end of the mouthpiece to permit the aerosolized drug formulation to be delivered to a  
4 patient upon inhalation through the second end of the mouthpiece.

1           17. A method for administering a drug formulation, the method  
2 comprising:  
3           providing a container having an amount of a drug formulation;  
4           preventing the transfer of the drug formulation from the container with an  
5 electronic lockout device when the lockout device is in an inactive state; and  
6           supplying electrical current to the lockout device to place the lockout  
7 device in an active state, thereby permitting the transfer of the drug formulation from the  
8 container.

1           18. A method as in claim 17, wherein the electronic lockout device  
2 comprises a lockout element that is positioned in a dose preventing position when in the  
3 inactive state, and further comprising moving the lockout element to a dosing permitting  
4 position when electric current is supplied to place the lockout device in the activated  
5 state.

1           19. A method as in claim 18, wherein the container comprises a  
2 canister having a metering valve and an actuator, wherein the canister is reciprocatably  
3 held within a housing between a home position and a dosing position, and further  
4 comprising depressing the canister into the housing to the dosing position to engage the  
5 actuator and to release a metered amount of the drug formulation when the lockout device  
6 is in the active state.

1           20. A method as in claim 19, further comprising preventing  
2 engagement of the actuator when the lockout element is in the dose preventing position.

1           21. A method as in claim 20, further comprising engaging the canister  
2 with the lockout element to prevent movement of the canister to the dispensing position  
3 when the lockout element is in the dose preventing position.

1           22. A method as in claim 21, further comprising disengaging the  
2 lockout element from the canister to permit movement of the canister to the dispensing  
3 position upon supply of the electrical current.

1           23. A method as in claim 20, further comprising engaging the lockout  
2 element with a stop that is positioned below the actuator upon supply of the electrical  
3 current, and further comprising depressing the canister into the housing to engage the  
4 actuator with the stop.

1           24. A method as in claim 18, further comprising stopping the supply of  
2 the electric current to the lockout device after the drug formulation has been transferred  
3 from the container.

1           25. A method as in claim 24, further comprising supplying electric  
2 current to the lockout device to permit another dosing only after a certain dosing  
3 conditions have been satisfied.

1           26. A method as in claim 25, further comprising counting the number  
2 doses transferred from the container.

1           27. A method as in claim 26, further comprising displaying whether  
2 the container contains an amount of drug formulation based on the number of counts.

1           28. A hand-held, portable, aerosol drug delivery system, comprising:  
2           a housing having a mouthpiece;  
3           a canister that is movable within the housing when manually depressed  
4 into the housing, the canister having a metering valve that is operable to release a metered  
5 amount of a drug formulation from the canister; and  
6           a control system to control opening of the valve such that the valve is only  
7 opened when a force is manually applied to depress the canister into the housing and  
8 when a dosing condition has been satisfied.

1           29. A system as in claim 28, wherein the control system comprises a  
2 controller and a locking mechanism, wherein the controller is configured to send a signal  
3 to the locking mechanism to permit opening of the valve once the dosing condition has  
4 been satisfied.

1           30. A system as in claim 29, wherein the dosing condition is the  
2 passage of a certain amount of time between dosings, and further comprising an  
3 electronic clock coupled to the controller to measure the passage of time between dosings.

1           31. A system as in claim 28, wherein the locking mechanism is  
2 normally in a dose preventing position and is movable to a dosing position when  
3 electrical current is supplied to the locking mechanism to permit opening of the valve  
4 when the canister is depressed.

1           32. A system as in claim 28, wherein the locking mechanism includes a  
2 locking element that engages the canister to prevent depression of the canister into the  
3 housing when in the dose preventing position.

1           33. A system as in claim 28, wherein the canister includes an actuator,  
2 and wherein the locking mechanism includes a locking element that engages a stop that in  
3 turn engages the actuator when in the dose permitting position and when the canister is  
4 depressed into the housing.

1           34. A method for administering a nicotine formulation for smoking  
2 cessation therapy, the method comprising:  
3                 providing an amount of a nicotine formulation;  
4                 preventing the aerosolization of the nicotine formulation with a lockout  
5 device when the lockout device is in an inactive state;  
6                 supplying electric current to the lockout device to place the lockout device  
7 in an active state; and  
8                 aerosolizing the nicotine formulation.

1           35. A method as in claim 34, further comprising controlling when  
2 electric current may be supplied to the lockout device based on a specified dosing  
3 schedule.

1           36. A system as in claim 1, wherein the drug formulation comprises  
2 nicotine.